REMARKS

Drawings

Please confirm that the amendments to the specification, and the previously submitted remarks, have overcome the previous objections to the drawings.

Rejections under 35 U.S.C. 112

Claims 58-62 were rejected under 35 U.S.C. 112, as indefinite. This rejection is respectfully traversed if applied to the amended claims. The claims have been amended to clarify when the claimed support material is formed of the claimed material. Claim 62 has been amended to delete "useful for". One skilled in the art would know that a material for spinal cord repair would be formed of a material and of a suitable shape for insertion into the spinal column at the site for repair.

Rejection under 35 U.S.C. 102

Claims 43 and 58-62 were rejected under 35 U.S.C. 102(e) as disclosed by U.S. Patent No. 5,776,747 to Schinstine ("Schinstine"). This rejection is respectfully traversed if applied to the amended claims.

As the examiner noted, the claimed support structure is immediately weight bearing and accommodates both compressive and tensile forces. This limitation has been inserted into the independent claims. See page 9 to the top of page 10 for support.

The following comments that were previously made are even more application. See, in particular, a quote from the specification, relating to the criteria for the support structure:

"The invention has many advantages. For example, upon gelling, the hydrogel-cell composition is supported by the support structure and forms a uniform suspension in which

nutrients can readily diffuse to the cells and waste products can diffuse away from the cells. As a result, the hydrogel keeps the cells viable and allows vascularization of the suspension, ultimately resulting in the growth of new tissue and its engraftment to the patient's body. The permeable support structure, into which the liquid hydrogel-cell composition is delivered, provides a shape and structure for the solidifying hydrogel-cell composition while still allowing nutrients and waste products to diffuse to and from the cells within the hydrogel. Thus, the *support structure guides the development and shape of the new tissue, and does so with the ability to resist external stresses from the environment and surrounding tissues*, i.e., the support structure is immediately weight-bearing, for example if the structure is used to replace a bone or cartilage. Moreover, the weight bearing characteristic of the support structure in bone or cartilage enables stresses to be transmitted across the hydrogel-cell suspension that will encourage bone or cartilage development in the hydrogel-cell suspension.

In the absence of such a support structure, a patient would not be able to apply any weight or stress to the hydrogel-cell composition because such forces would cause the hydrogel-cell composition to become distorted and displaced. This is similar with any replacement of structural tissues which are exposed to stress, such as ligaments, tendons, and bones anywhere within the body. Note also that the support structure accommodates not only compressive forces but also tensile forces, such as when one pulls on a tendon or stretches skin. In such cases, the support structure mimics the elasticity of the tendon or skin, and has ends that are typically sutured or adhered to adjacent tissue.

Composite support structures are also possible. For example, one can create a support structure that has a hollow tube of solid material, e.g., coral, on the outside loaded with a

hydrogel-osteoblast (or other bone precursor cells) composition, and a softer support in the center such as a fiber mesh loaded with a hydrogel-spinal cord stem cell composition.

Also, the support structure maintains the structural integrity and the desired shape of the hydrogel-cell composition without altering the physical characteristics of the hydrogel-cell composition in ways that can harm the cells and limit the diffusion of nutrients and waste products to and from the cells.

Furthermore, the support structure can be designed to be compressible and resilient so that it can be easily implanted into a patient through, for example, a cannula, endoscope, or arthroscope. Thus, the support structure can be cut or molded into the shape of the desired tissue to be grown, implanted into the patient in a deformed state through a cannula, allowed to expand within the desired body cavity, and subsequently injected with the liquid hydrogel-cell composition. The subsequent growth of new tissue will take the shape of the support structure." (emphasis added to show basis for claim amendments)

The claims have been amended to incorporate these requirements of the support structure for providing support as well as guidance for formation of the cells. No where does Schinstine disclosure such a support structure - indeed, Schinstine teaches away from such a structure since Schinstine's goals are very different, that is not to form new tissue within the body but to provide metabolic supplementation or replacement. To the extent a support structure is incorporated, it is to promote attachment, proliferation and function of the cells, not to provide immediate weight bearing function and guide new tissue formation.

Allowance of claims 43, 44 and 54-62 as amended is earnestly solicited.

Respectfully submitted,

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